5052

HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124292
Facility ID: 150482
Inspection ID #1504820007

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

01-BLT-09

January 9, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Joan E. Berkowitz, Medical Director
Northwest Hospital Center
5401 Old Court Road
Randallstown, Maryland 21133

Dear Dr. Berkowitz:

A representative from the State of Maryland under contract to the Food and Drug Administration (FDA) inspected your facility on December 15, 2000. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Your facility failed to document that processor quality control was performed 16 out of 22 days of operation in the month of April 2000.**

- **Your facility failed to document that processor quality control was performed for 16 consecutive processing days in the month of April 2000.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 findings because they represent a failure to comply with a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 finding was listed on the inspection report provided to you at the close of the inspection:

- **Your facility failed to perform corrective action when phantom image scores, phantom background optical density, or density difference, fell outside the allowable regulatory limits for phantom image tests conducted on your facility's mammography units located in rooms 1, 2, and 3.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.

- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to:

Food and Drug Administration
Richmond Resident Post
10710 Midlothian Turnpike, Suite 424
Richmond, Virginia 23235
Attn: Scott J. MacIntire
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District